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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/745,243	12/21/2000	Narendra Parikh	JBP514	8350

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EXAMINER	
HOLT, ANDRIAE M	
ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/745,243	PARIKH ET AL.	
	Examiner	Art Unit	
	Andriae M. Holt	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-6,8,9,11,13,14,16-19,21,22,24,31-33,35,36 and 73-76* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-6,8,9,11,13,14,16-19,21,22,24,31-33,35,36 and 73-76* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/6/2011*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 6, 2010 has been entered.

Claims 2-6, 8-9, 11, 13-14, 16-19, 21-22, 24, 31-33, 35-36, and 73-76 are pending in the application. Claims 8, 31, and 73 have been amended. Claims 2-6, 8-9, 11, 13-14, 16-19, 21-22, 24, 31-33, 35-36, and 73-76 will presently be examined to the extent they read on the elected subject matter of record.

Information Disclosure Statement

Information Disclosure Statement filed October 6, 2011 is acknowledged.

Status of the Claims

Rejections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Objections

Claim 24 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 16. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is

proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4, 6, 8-9, 11, 14, 31, 35, and 73 are rejected under 35 U.S.C. 102(b) as being anticipated by Yang et al. (US 5,576,022).

Yang et al. disclose controlled release tacrine drug delivery systems comprising an immediate release composition and a sustained release composition wherein 1) the immediate release composition comprises in percentages by weight of the immediate release composition: (A) immediate release pellets comprising: (a) nonpareil seeds in an amount from about 25% to about 75%; (b) tacrine in an amount from about 10% to about 80%; and (c) a binding agent in an amount from about 1% to about 10%; and (B) a sealing layer over the immediate release pellets comprising: (a) a sealing agent in an amount up to about 6%, and (b) a first plasticizing agent in an amount up to about 5%. Yang et al. disclose that the sustained release composition comprises in percentages by weight of the sustained release composition: (A) the immediate release composition; and (B) a sustaining layer over the immediate release composition comprising; (a) a water-insoluble polymer in an amount from about 40% to about 90%; (b) a water-soluble polymer in an amount up to about 10%; and (c) a second plasticizing

agent in an amount up to about 10%; wherein the sustaining layer and the immediate release composition are present in the sustained release composition in a ratio by weight from about 1:9 to about 4:6, respectively, and the immediate release composition and the sustained release composition are present in the drug delivery system in a ratio by weight from about 0.01:1 to about 1:1, respectively (col. 2, lines 14-54). Yang et al. disclose that the water-insoluble polymer provides a diffusion barrier for tacrine and controls its release rate and the water-soluble polymer increases the permeability of the sustaining coat. Yang et al. disclose that they have discovered that by carefully controlling the ratio of water-soluble polymer to water-insoluble polymer in the sustained release composition, the release characteristics of tacrine capsules can be optimized (col. 3, lines 58-65).

Yang et al. disclose in col. 14, lines 30-56, Formulation No. 40 (Sustained Release Pellets in CR4 Capsule) Core Pellets Tacrine Hydrochloride Monohydrate; Sugar Spheres NF; Povidone USP; Spray Talc; Purified Water USP (core containing active ingredient)

Sustained Coating Ethylcellulose Dispersion NF (30% solids); Triethyl Citrate FCC; Spray Talc; Purified Water USP (first coating layer comprised of taste masking agent, insoluble film forming polymer, ethylcellulose)

Overcoat Coating Hydroxypropyl Methylcellulose 2910 USP; Polyethylene Glycol 3350 NF; Spray Talc; Purified Water USP (second coating layer on surface of first coating layer, water-insoluble film forming polymer, hydroxypropyl methylcellulose, and anti-grit agent, polyethylene glycol).

Yang et al. disclose in the formulation for CR4 Capsules (Formulation 40), the SR2 Pellets (Formulation 40) were prepared in a similar manner as that described for Formulation 39. The SR coating formulation consisted of ethylcellulose aqueous dispersion (38.08% w/w), triethyl citrate (3.34% w/w), spray talc (0.15% w/w), and water (58.34% w/w). The SR coating formulation was applied to the core pellets to 15% weight increase. The ethylcellulose coated pellets were subsequently overcoated with the same overcoat formulation as described for Formulation 39 and cured similarly using the same equipment (col. 12, lines 46-60).

Yang et al. disclose water-soluble polymers useful in the sustaining layer include cellulose derivatives such as hydroxypropyl cellulose, hydroxypropyl methylcellulose, sodium carboxymethylcellulose (water soluble film forming polymers) (col. 6, lines 51-56). Yang et al. disclose that the amount of water-soluble polymer in the sustained release composition is an effective amount to prepare a sustaining layer. An effective amount of a water-soluble polymer is an amount which will increase the permeability of the sustaining coat and thereby control its release rate. Yang et al. disclose that the amount of water-soluble polymer is a matter of preference, subject to such factors as the type of water-soluble polymer employed, the exact type and amount of water-insoluble polymer employed, and the other ingredients in the drug delivery system. Thus, the amount of water-soluble polymer may be varied in order to obtain the result desired in the final product (col. 6, lines 57-67-col. 7, line 1). Yang et al. disclose that once prepared, the controlled release tacrin drug delivery systems may be stored for future use or may be formulated with conventional additives such as pharmaceutically

acceptable carriers to prepare a wide variety of medicated controlled release compositions to suit particular applications (col. 9, lines 8-12). Yang et al. disclose that to achieve acceptable stability and quality, as well as, good taste and mouth feel in a controlled release formulation several considerations are important. These considerations include the amount of active substance per tablet, the flavoring agent employed, the degree of compressibility of the tablet, and the organoleptic properties of the pharmaceutical composition (col. 10, lines 48-54).

In reference to the limitation that the second coating does not retard the dissolution of the active ingredient, it is noted that the second layer (overcoat layer) disclosed by the prior art is the same as the second layer disclosed in the instant application, i) a water soluble film forming polymer; and ii) an anti-grit agent selected from the group consisting of polyethylene glycol. The ratio of water soluble film forming polymer to anti-grit agent of the prior art is within the same ratio range as disclosed in the instant application 20:80 to about 80:20. Therefore, it would be inherent that the second coating layer of the prior art would have the same property of not retarding the dissolution of the active agent, as disclosed in the instant application. In addition, Yang et al. disclose that the overcoat layer is the same as the immediate release film coating of formulation 37 (col. 11, line 30, lines 65-67-col. 12, lines 1-6 and col. 12, lines 55-57). As such, as an immediate release polymer layer, it would not affect the dissolution of the active agent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2, 4-6, 8-9, 11, 13-14, 16-19, 21-22, 24, 31, 33, 35-36, and 73-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over CA 2,068,366 in view of Kanai et al. (US 4,868,183) and Uchida et al. (US 5,215,999) in further view of Yang et al. (US 5,576,022).

Applicant's Invention

Applicant claims a textured masked particle comprising a) a core containing an active ingredient, b) a first coating layer comprised of a taste masking agent that substantially covers the core, and c) a second coating layer on the surface of the first coating layer. Applicant claims the taste masking agent is comprised of an insoluble film forming polymer. Applicant claims the second coating layer is comprised of i) a water soluble and/or water swellable film forming polymer; and ii) an anti-grit agent selected from the group consisting of polyethylene oxide, polyethylene glycol, and mixtures thereof. Applicant claims the weight ratio of water soluble and/or water swellable film

forming polymer to anti-grit agent in the second coating layer is in the range of about 20:80 to about 80:20.

Determination of the scope of the content of the prior art (MPEP 2141.01)

CA 2,068,366 teaches a taste-masked free-flowing powder including microcapsules having a particle size of 300 μm or less that includes a core element including at least one pharmaceutically active ingredient; a substantially smooth and continuous microcapsule coating on the core element formed from a coating composition including a water insoluble polymer (page 3, lines 1-11). CA 2,068,366 teaches a taste-masking microcapsule powder composition may be in the form of sprinkles, tablets; including chewable tablets and lozenges. CA 2,068,366 teaches the pharmaceutical composition may be provided in the form of dispersible or effervescent tablets (page 8, lines 12-20). CA 2,068,366 teaches the water insoluble polymer may be selected from ethyl cellulose and cellulose acetates (water insoluble polymers) (page 8, lines 26-32). CA2,068,366 teaches in one embodiment the taste-masked microcapsule coating composition may include the coating composition of a water insoluble polymer, one or more enteric polymer (enteric polymer), an acid-soluble (reverse enteric) polymer, and a partially water soluble polymer (water soluble polymer). CA 2,068,366 teaches the enteric polymer is selected from cellulose acetate phthalate, hydroxypropyl methyl cellulose phthalate (HPMCP), polyvinyl acetate phthalate, or hydroxypropyl methylcellulose acetate succinate (specific enteric polymers) (page 9, lines 19-38). CA 2,068,366 teaches when the microcapsule coating is a sustained release coating the

coating may include a water insoluble polymer (water insoluble polymer); an enteric polymer (enteric polymer) and a partially water soluble component (water soluble polymer) (page 10, lines 4-12). CA 2,068,366 teaches the partially water-soluble component may be selected from hydroxypropyl methylcellulose, polyethylene glycol and mixtures thereof (hydroxypropyl methylcellulose and polyethylene glycol) (page 10, lines 13-18). CA 2,068,366 teaches the modified release core coating contains a water insoluble polymer; an acid-soluble (reverse enteric) polymer and a partially water soluble component (page 10, lines 27-35). CA 2,068,366 teaches the modified release may provide substantially no or a slow rate of release at alkaline pH, but substantially immediate or more rapid release at acid pH (page 10, lines 19-16).CA 2,068,366 teaches the reverse enteric polymer is selected from the acrylate copolymer sold under the trade designation Eudragit E100 or natural polymers such a Chitin (page 11, lines 2-8) (non enteric water soluble polymer). Eudragit E100 is a cationic copolymer based on dimethylaminoethyl methacrylate and neutral methacrylic ester as evidenced by the EUDRAGIT® E100 specification sheet.

CA 2,068,366 teaches the microcapsule compositions may include carriers or excipients (page 11, lines 23-31). CA 2,068,366 teaches the microcapsule composition can be used with acetaminophen, theophylline, ranitidine hydrochloride, and NSAIDS (page 8, lines 2-8). CA 2,068,366 teaches the method for preparing the microcapsules on page 13, lines 1-23).

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

CA 2,068,366 does not teach the second coating layer is comprised of a water

soluble and/or water swellable film forming polymer and an anti-grit agent such as polyethylene oxide or polyethylene glycol or the claimed ratios. It is for this reason Kanai et al., Uchida et al., and Yang et al. are added as secondary references.

The teachings of Yang et al. with respect to the 35 U.S.C. 103(a) rejection is hereby incorporated and are therefore applied in the instant rejection as discussed above.

Kanai et al. teach in preparation example 2, compound 1, crystalline cellulose, corn starch and magnesium stearate were ground and formulated into tablets with use of sugar-coated punch having a radius of 8 mm. Kanai et al. teach that the resulting tablets were coated with a film coating agent consisting of hydroxypropyl methyl cellulose (hydroxypropyl methyl cellulose), polyethylene glycol 6000 (polyethylene glycol), castor oil and ethanol, giving film-coated tablets of the composition (col. 39, lines 20-27).

Uchida et al. teach that the N-2-propenyl-4-[(2-ethylphenyl)amino]-8-methoxyquinoline-3-carboxamide hydrochloride compound, AVICEL, corn starch and magnesium stearate were mixed, polished and then tableted by means of a R10mm punch (for sugar-coated tablets). Uchida et al. further teach the tablets thus obtained were coated with a film comprising hydroxypropyl methyl cellulose (hydroxypropyl methyl cellulose), polyethylene glycol-6000 (polyethylene glycol), castor oil and methanol to prepare film-coated tablets (col. 64, lines 1-19).

Finding of prima facie obviousness
Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of invention to use the teachings of CA 2,068,366, Kanai et al., Uchida et al., and Yang et al. and use a water soluble and/or water swellable film forming polymer and an anti-grit agent such as polyethylene oxide or polyethylene glycol as the second layer. CA 2,068,366 teaches various formulations of active ingredients/agents formulated with a water insoluble polymer to mask taste. The formulations that are taught by CA 2,068,366 include insoluble polymers that form films, enteric polymers, and water soluble polymers that also form films. One skilled in the art at the time the invention was made would have been motivated to use a water soluble polymer such as hydroxypropyl methylcellulose and an anti-grit agent such as polyethylene glycol as the second coating because as evidenced by Kanai et al. and Uchida et al. these ingredients are used to prepare film-coated tablets and particles as evidenced by the teaching of Yang et al. As such, the skilled artisan would have been motivated to try a film-coating formulation that is well-known in the art, especially when the ingredients of the film-coating formulation can be used to prepare to the active agents with two coatings.

In reference to the claimed ratios of 20:80 to about 80:20, 50:50, and 60:40 to about 40:60. Kanai et al. and Uchida et al. each teach that hydroxypropyl methyl cellulose and polyethylene glycol are mixed at a 3:1 or 66.7:33.3. This ratio would fall within the range of 20:80 to about 80:20. In addition, absent data showing unexpected results, as noted in the previous office action, the use of the ratio would be a matter of

routine experimentation and optimization. Accordingly, this type of modification would have been well within the purview of the skilled artisan and no more than an effort to optimize results.

Therefore, the claimed invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made because every element of the invention has been fairly suggested by the cited reference.

Response to Arguments

Applicant's arguments filed October 6, 2010 have been fully considered but they are not persuasive. Applicant argues that neither Kanai et al. nor Uchida et al. disclose or suggest the current claimed coated particles or methods of manufacturing coated particles. In response to Applicant's arguments, as noted in the previous office actions, Kanai et al. and Uchida et al. were used as evidence to teach that a water soluble and/or water swellable film forming polymer and an anti-grit agents such as polyethylene oxide or polyethylene glycol are used as second layers in the preparation of pharmaceutical formulations. The primary reference, CA 2,068,366, teaches active ingredient particles that are coated with two layers, a water insoluble polymer and a water soluble polymer. One skilled in the art at the time the invention was made would have motivated to use a water soluble polymer such as hydroxypropyl methylcellulose and an anti-grit agent such as polyethylene glycol as the second coating in the formulations taught by the primary references because Kanai et al. and Uchida et al. teach these ingredients are used to prepare film-coated tablets. While, tablets are not particles, the technology of film coating particle or tablets with the same compounds or

combinations of compounds is well known and documented in the art, as evidenced by the teachings of Yang et al. which teach the use of a mixture of hydroxypropyl methylcellulose and polyethylene glycol as a second coating of particles. As such, the skilled artisan would have been motivated to try a film-coating formulation that is well-known in the art, especially when the ingredients of the film-coating formulation can be used to prepare the coating layers used in the formulations taught by the primary reference, CA 2,068,366.

In response to Applicant's argument that Kanai et al. and Uchida et al. do not disclose or suggest the current claimed methods of manufacturing coated particles, Kanai et al. and Uchida et al. were used as evidence to teach that a water soluble and/or water swellable film-forming polymer and an anti-grit agents such as polyethylene oxide or polyethylene glycol are used as second layers in the preparation of pharmaceutical formulations. The primary reference, CA 2,068,366, teach the method of manufacturing coated particles. CA 2,068,366 teaches the method for preparing the microcapsules on page 13, lines 1-23.

Applicant also argues that CA 2,068,366 does not teach or suggest that the second coating layer does not retard the dissolution of the active ingredient. In response to Applicant's argument, while CA 2,068,366 does recite the microparticles having a "reduced dissolution profile", it also teaches an embodiment, wherein the particles have a modified release coat. The modified release coat provides substantially no or slow rate of release at alkaline pH, but substantially immediate or more rapid rate of release at acid pH. The components of the modified release coating include a water insoluble

polymer, an acid-soluble (enteric) polymer and a partially water soluble component, which includes hydroxypropyl methylcellulose. Therefore, based on this teaching it would have been obvious to the skilled artisan that the coatings can be modified or varied in order to obtain the result desired in the final product, a slow release formulation or a rapid release formulation.

In response to Applicant's purported unexpected results, the reported results are not commensurate in scope with Applicant's claims. Applicant claims a texture masked particle comprising a) a core containing an active ingredient, b) a first coating layer comprised of a taste masking agent that substantially covers the core, and c) a second coating layer on the surface of the first coating layer. Applicant claims the taste masking agent is comprised of an insoluble film forming polymer. Applicant claims the second coating layer is comprised of i) a water soluble and/or water swellable film forming polymer; and ii) an anti-grit agent selected from the group consisting of polyethylene oxide, polyethylene glycol, and mixtures thereof. Applicant claims the weight ratio of water soluble and/or water swellable film forming polymer to anti-grit agent in the second coating layer is in the range of about 20:80 to about 80:20. The formulation of the instant invention prepared comprises preparation of particles comprising acetaminophen as the active ingredient, ethyl cellulose as the insoluble film forming particle of the first coating, and hydroxypropyl methylcellulose and polyethylene glycol 8000 as the texture masking or second layer. Acetaminophen represents a single species of active ingredients, as claimed. Ethylcellulose represents a single species of insoluble film forming polymers. Hydroxypropyl methylcellulose represents a single

species of water soluble and/or water swellable film forming polymers. The examiner cannot determine if the purported unexpected results of "less grittiness" provided by the combination of acetaminophen, ethylcellulose, hydroxypropyl methylcellulose and polyethylene glycol 8000 is reflective of the combination of any active ingredient, any water insoluble film-forming polymer, any water soluble film-forming polymer, and any anti-grit agent, known and unknown. In addition, Applicant's independent claims are directed to particles and method of making particles and not chewable tablets, as tested in the examples. Therefore, the examiner notes that the claims are not commensurate in scope with the examples provided.

None of the claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andriae M. Holt whose telephone number is (571)272-9328. The examiner can normally be reached on 7:00 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richter Johann can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/John Pak/
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